Lasers in Surgery and Medicine 19:90–96 (1996)

# Results of a Clinical Trial of the Holmium:YAG Laser in Disc Decompression Utilizing a Side-Firing Fiber: A Two-Year Follow-Up

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***Background and Objective:*** **Laser-assisted disc decompression (LADD) is an operative technique for the treatment of symptomatic, nonsequestered herniated nucleus pulposus that has failed to respond to conservative treatment. The current study reports 2-year follow-up data.**

***Study Design Materials and Methods:*** **Patients were evaluated by an independent interviewer postoperatively, and at 1 week, 3 months, 6 months, 1 year, and 2 years. Ratings were based upon the modified Macnab criteria. All patients evidenced primarily leg pain with or without back pain that had failed a minimum of 6 weeks of conservative treatment. Patients with lateral recess or central stenosis, sequestered discs, or predominantly scar tissue from a previous discectomy were not considered candidates for LADD.**

***Results:*** **Utilizing postoperative follow-up at 2 years, a surgical success rate of 86.9% was achieved. For patients requiring an additional LADD procedure, results at 6-month follow-up yielded a surgical success rate of 80%.**

***Conclusion:*** **LADD appears to be a viable treatment modality for symptomatic, nonsequestered lumbar disc herniation recalcitrant to conservative treatment. LADD may represent a more cost-effective and safer alternative to traditional surgical procedures.** 

**Key words: holmium: YAG laser, lumbar disc disease, Macnab criteria, side-firing fiber**

## INTRODUCTION

Laser-assisted disc decompression (LADD) is an operative technique for the treatment of symptomatic, nonsequestered herniated nucleus pulposus that has failed conservative treatment. A variety of theoretical advantages have been suggested for using laser energy for intradiscal ablation and subsequent pressure reduction, as opposed to alternative procedures. These include ease of access to the disc space and more predictable tissue ablation [1]. In addition, this surgical technique is less invasive than traditional open laminectomy and discectomy and is potentially more advantageous in terms of decreased patient recovery time, less morbidity, lower medical costs, and faster return to full activity.

Traditionally, the treatment for symptomatic, nonsequestered herniated nucleus pulposus, which has been unresponsive to conservative care, has included either open laminectomy and/or discectomy [2]. Open laminectomy and discectomy typically require between 2 and 7 days of postsurgical hospitalization and carry inherent

Accepted for publication December 29, 1995.

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risks for significant blood loss, residual scar formation, damage to neural or retroperitoneal structures, and infection [3]. With the advent of percutaneous methods of intervertebral disc decompression, these potential problems have been lessened considerably [2,4,5]. Schaeffer and Kambin [4] have shown that a minimally invasive procedure (i.e., arthroscopic microdiscectomy) resulted in "excellent" and "good" results in 87% of their patients, as defined by the modified Macnab criteria. In addition, operative failures were analyzed, thereby delineating which patients were less likely to respond to a nontraditional approach to lumbar disc herniation.

Little research has been conducted to date using LADD procedures in clinical trials. Choy [6] utilized the Nd:YAG laser on 299 patients and has reported a 75% success rate. Quigley and Maroon [1] noted that other clinical trials have been attempted, but with small numbers of patients and with little available follow-up information. Indeed, some previous clinical trials have shown LADD to have less potential for perineural scarring, intraoperative blood loss, and infection [2]. Conversely, LADD procedures have been criticized by some researchers. Mathews [7] has noted relatively poor long-term success rates using the KTP fiberoptic system and a relatively high rate of complications. However, he notes that more rigorous patient selection procedures might improve success, and it may be that complications are a function of using of the KTP laser and associated wavelength.

The biological and histological changes resulting from LADD at various wavelengths have been reported by several investigators [8,9,10]. The theoretical advantages of a side-firing fiber have also been suggested [11,12]. Uppal and Smith [11] concluded that a side-firing fiber may be more efficacious in terms of tissue ablation and subsequent intradiscal pressure reduction, as well as more accurate in terms of direction of the laser beam itself when compared to the straight-firing fiber. In addition, investigators have reported the Holmium:YAG laser to be a more viable modality for LADD due to its 2.1 μm wavelength, resulting in a very high absorption in water, and water containing tissues such as the intervertebral disc [12].

In the current clinical setting, the Holmium: YAG laser and side-firing fiber was utilized to treat patients with nonsequestered, herniated nucleus pulposus previously unresponsive to conservative treatment. A preliminary report of the first 223 patients yielded a surgical success rate of 84% at 1 year follow-up [13]. The current study reports 2-year follow-up for patients treated operatively between February 1992 and February 1993. Data are provided within target groups, including workers compensation patients, individuals who have undergone previous operative care, and individuals requiring an additional LADD. Differences in surgical outcome at 1- and 2-year follow-up are examined.

## METHODS

### Patient Selection

Patients were selected based upon the persistence of positive neurologic signs and symptoms compatible with nonsequestered, herniated nucleus pulposus (i.e., totally subtransligamenteous herniation with disc material contained within the annulus) [5]. Before physical examination and consideration for inclusion in this study, each patient was asked to complete a pre-operative patient history form that addressed the onset and nature of their symptoms, previous forms of treatment attempted, and other related neurologic conditions for which the patient had been treated. Correspondent to this form, the patient completed a diagram/illustration to indicate the specific area(s) of discomfort, type of pain (e.g., ache, numbness, pins and needles, burning, or stabbing), and the radicular components of their discomfort.

Based upon the above complaints and physical examination indicating radicular injury, as well as radiographic confirmation of contained disc herniation or prolapse, it was then determined whether or not the patient was a candidate for the study. No patient was considered for surgical intervention if the primary source of neurologic findings was felt to be due solely to scar tissue from a previous discectomy, lateral recess or central stenosis, or sequestered disc material (i.e., totally transligamenteous herniation with disc material separate and apart from the annulus).

All patients had received a minimum of 6 weeks conservative treatment, including nonsteroidal anti-inflammatory drugs (n = 80), physical therapy (n = 31), selective nerve blocks (n = 30), epidural steroids (n = 18), and in some cases chiropractic care (n = 8). Patient selection was not based upon age, sex, employment status, duration of symptoms beyond the minimum 6 weeks conservative trial, or the presence of recurrent disc herniation. No patient was selected out of the

**TABLE 1. Modified Macnab Criteria**

| Surgical success | |
|---|---|
| Excellent | Good |
| Free of pain | Occasional nonradicular pain |
| No restriction of mobility | Relief of presenting symptoms |
| Able to return to normal work and activities | Able to return to modified work |
| **Surgical failure** | |
| Fair | Poor |
| Some improved functional capacity | Continued objective symptoms of root involvement |
| Still handicapped and/or unemployed | Additional operative intervention needed at the index level, irrespective of repeat or length of postoperative follow-up. |

study due to the presence of a workers' compensation claim.

## MATERIALS

All procedures were performed using the OmniPulse Holmium:YAG laser with the Sidefire™ laser fiber, which contained a proprietary, 550-μm diameter optical fiber, manufactured by Trimedyne (Irvine, CA).

### Procedure for Laser-Assisted Disc Decompression

The patient was placed in the prone position on a radiolucent operating table with pressure points cushioned and the patient's back flexed to decrease lumbar lordosis. A C-arm fluoroscope with image intensification was used to provide images in both the anterior/posterior and lateral views to verify position of the laser. An attempt was always made to place the laser postero-lateral or central at the level of pathology, subannular to the herniation. The procedure was performed under local anesthesia, utilizing Marcaine and Xylocaine with Epinephrine, and patients were monitored by an anesthesiologist. All patients were awake and able to converse freely throughout the procedure.

A standard posterolateral approach from the side of the herniation was made, utilizing a stab wound with a #11 blade. Guidewire placement within the appropriate interspace was accomplished and the Omni™ Spinal Introduction System (Trimedyne) was utilized for placement of the side-firing laser fiber. The laser parameters were 13 watts at 10 hertz, and energy was delivered (M joules = 1,296.49) until the patient's subjective response indicated complete relief of radicular pain.

### Laser Technique

Initially, the laser energy was applied for 10 seconds on and 10 seconds off, and the laser fiber was fixed at 12, 3, 6, and 9 o'clock, producing an oval ablation zone. However, after experiencing patient complaints of heat during LADD, the procedure was changed to 5-second intervals and the direction of the side-firing fiber was adjusted to 2, 4, 8, and 10 o'clock. Procedural adjustments were made to decrease the possibility of thermal damage to the vertebral end plate(s).

### Follow-Up

Evaluations were carried out by an independent interviewer via direct telephone communication, and their current status was rated based upon the modified Macnab criteria (see Table 1) [14]. Patients who gave an ambiguous response were given a less favorable rating. Macnab ratings of excellent and good were deemed surgical *successes* for the purposes of this study, whereas outcomes of fair and poor were deemed surgical *failures*. Also, patients requiring open laminectomy or an additional LADD at a recurrent level (i.e., index level) were classified as failures for the initial LADD. Patients were evaluated postoperatively, and again at 1 week, 3 months, 6 months, 1 year, and 2 years. Although direct interviewer-patient follow-up would have been desirable, many patients commute a considerable distance for medical follow-up by the surgeon, and it would be unreasonable to request patients to make additional trips for direct interviews. The telephone interview was strictly formatted, however, assuring standardized questioning.

Postoperatively, patients were treated on an individual basis in terms of release to full activity and need for further treatment. For all patients, it was suggested that no prolonged sitting in a

straightback chair or heavy lifting be done within the 4–6-week interval following LADD. All patients were encouraged to begin ambulation immediately and to follow a daily exercise program of continuous walking for at least 20 minutes.

## RESULTS

Of the 100 patients, 50% (n = 50) were male and 50% (n = 50) were female. Age of the patients ranged from 18 to 75 years, with a mean of 43.3 (SD = 12.29). One female patient was deceased at 2-year follow-up. Biographical and procedural data were included in the description of the patient sample; however, this patient was excluded from analysis of surgical outcome at 2-year follow-up. Surgical outcome (i.e., surgical success/surgical failure) was not dependent upon gender of the patient [$X^2$ (1) = .07, $P$ = .80]. A 2 × 2 (surgical outcome × gender) analysis of variance (ANOVA) was conducted to examine for differences in age between males (M age = 43.0) and females (M age = 44.8), and surgical success (M age = 42.9), and surgical failure (M age = 45.0). The analysis yielded no significant interaction ($F_{1,95}$ = .18, $P$ = .67), or main effects for gender ($F_{1,95}$ = .18, $P$ = .67) or surgical outcome ($F_{1,95}$ = .31, $P$ = .58).

There was a preponderance of left-sided lesions, with 59% (n = 59) left-sided and 41% (n = 41) right-sided. No decompressions were performed at the L1–2 level, however, 9% (n = 1) were performed at L2–3, 3.8% (n = 4) at L3–4, 46.7% (n = 49) at L4–5, and 48.6% (n = 51) at L5–S1. Five patients had two levels decompressed during the same surgical procedure. Surgical outcome was not dependent upon level(s) of the procedure, $X^2$ (4) = 8.33, $P$ = .08.

Duration of symptoms prior to LADD was determined in 93% (n = 93) of the patients, ranging from 6 weeks to 30 years (median = 3.6 months); with 54% (n = 54) of the patients reporting a duration between 6 weeks and 6 months, 13% (n = 13) between 6 months and 1 year, 7% (n = 7) between 1 and 2 years, and 19% (N = 19) > 2 years. Those respondents who could not give a definitive onset of symptoms were coded with a missing value for this variable. There were no significant differences in duration of patient symptomatology for surgical outcome ($F_{1,88}$ = 3.21, $P$ = .07), with an average duration of 22.7 months (SD = 51.4).

Preoperative neurologic findings from physical examination indicated that 62% (n = 62) of the patients had diminished strength of the extensor hallicus longus (EHL), and 42% (n = 42) experienced diminished deep tendon reflex (DTR) (i.e., ankle or knee jerk). A positive straight leg raise (SLR) was determined in the right leg for 24% (n = 24) of the patients, left leg for 51% (n = 51), and bilateral for 3% (n = 3) of the patients. Analysis utilizing Chi square indicated that surgical outcome was not dependent upon EHL [$X^2$ (1) = .01, $P$ = .91]; DTR [$X^2$ (1) = .09, $P$ = .77]; or SLR [$X^2$ (1) = .01, $P$ = .97]. Positive radiographic findings of nonsequestered, herniated nucleus pulposus were determined by MRI (n = 91), CT (n = 5) or CT with myelogram (n = 4). Surgical outcome was not dependent upon type of radiographic imaging device [$X^2$ (2) = 1.35, $P$ = .53].

All patients, including those requiring an additional LADD, were released to full activity, with 68% (n = 68) released within 30 days following LADD, 19% (N = 19) released between 30–60 days, 4% (n = 4) released between 60–90 days, 8% (n = 8) released between 90–180 days and 1% (n = 1) released within 1 year.

Of the total patient sample, 73% (n = 73) were employed upon entering the study, and 35.6% (n = 26) of the employed patients were coded as worker's compensation cases. Approximately 8% (n = 6) of the employed patients were disabled (i.e., unable to work), including five workers compensation cases (WC) and one nonworkers compensation case (NWC). Macnab ratings at 2-year follow-up revealed that surgical outcome was not dependent upon WC/NWC related injuries [$X^2$ (1) = 1.56, $P$ = .21], with surgical success ratings of 84.6% and 93.6% for workers compensation and nonworkers compensation patients, respectively. Analysis of variance yielded no significant differences between WC/NWC related injuries for duration of symptoms ($F_{1,65}$ = .30, $P$ = .59) or number of days to release to full activity ($F_{1,69}$ = 2.32, $P$ = .13); however, there was a significant difference for number of days followed by the surgeon, with WC patients being followed significantly more days, $F_{1,67}$ = 16.53, $P$ = .01 (see Table 2 for means and standard deviations).

Seventeen of the 100 patients in the current study reported to have undergone previous operative care, including open laminectomy (n = 15), posterolateral fusion (n = 4), and chemonucleolysis (n = 1). The initial LADD was performed at recurrent levels for 76.4% (n = 13) of these patients. Analyses utilizing Chi square indicated that surgical outcome was not dependent upon

**TABLE 2. Worker's Compensation/Nonworker's Compensation**

| | WC | NWC |
|---|---|---|
| Duration of symptoms (months) | 16.96 (34.71) | 24.60 (64.16) |
| Days to release to activity | 42.12 (63.40) | 26.04 (25.03) |
| Days followed by surgeon | 162.92 (121.62) | 69.31 (69.99)* |

*$P<.01$.

type of previous operative care [$X^2$ (3) = .94, $P$ = .81], nor was outcome dependent upon level of previous operative care (i.e, recurrent or nonrecurrent) [$X^2$ (1) = .49, $P$ = .49]. However, a significant difference was found for the number of joules, with patients who had undergone previous operative care requiring a significantly lower number of joules (M = 1097) than patients with no previous operative care (M = 1337), $F_{1,98}$ = 4.81, $P$ = .03.

Notably, 19 of the 100 patients within the current study were recommended for open laminectomy by a neurosurgeon or orthopaedic surgeon. The recommendations were made independent from the author and prior to consideration for LADD and patients subsequently elected to undergo LADD. Of these patients, 84.2% (n = 16) responded with ratings of "excellent" or "good," and 15.8% (n = 3) were deemed surgical failures, including one patient who required open laminectomy for undetected sequestered herniation and two patients who required an additional LADD procedure at index level.

Macnab ratings from the initial LADD yielded a surgical success rate of 86.9% (n = 86) at 2-year follow-up. Surgical failures included patients with ratings of fair or poor (n = 4), patients requiring an additional LADD at a recurrent level (n = 5), and patients requiring open laminectomy for treatment of sequestered, herniated nucleus pulposus (n = 4).

Ten patients underwent second procedures, with 50% (n = 5) at the index level from LADD 1. Macnab ratings for LADD 2 at 6-month follow-up yielded a surgical success rate of 80% (n = 8). Surgical failures included patients with Macnab ratings of fair or poor (n = 2). Outcome from the additional LADD was not dependent upon the level of the initial LADD (i.e., index or additional level), $X^2$ (3) = 2.00, $P$ = .57. No significant differences were found for number of joules utilized in the additional LADD for patients whose procedures were performed at an index level (M = 1,345) vs. an additional level (M = 1150), $F_{1,8}$ = 1.71, $P$ = .23.

Comparing surgical outcome ratings between 1- and 2-year follow-up, surgical success ratings of 84% and 86.9% were attained, respectively. Paired sample t-tests indicated that there were no significant differences in surgical outcome at 1- and 2-year follow-up, t(98) = −1.42, $P$ = .16). Exploratory analyses were conducted to examine for changes between 1- and 2-year follow-up data. Examination of the data revealed that 25.3% (n = 25) of the sample had either improved (11.1%; n = 11) or declined (14.1%; n = 14) between 1- and 2-year follow-up. Nine patients improved from good to excellent, and two patients improved from fair to good. Thirteen patients declined from excellent to good, and one patient declined from fair to poor. Thus the change in surgical success ratings between 1- and 2-year follow-up (i.e., 84–86.9%) was a function of the patients who improved from fair to good (i.e., failure to success).

## DISCUSSION

The findings of the current study suggest that using the Holmium: YAG laser and side-firing fiber for LADD potentially provides a safe and efficacious method of treatment for patients with nonsequestered, herniated nucleus pulposus previously unresponsive to conservative treatment. Although one initial procedure was aborted due to difficulty accessing the L5-S1 interspace of an obese patient, the procedure was performed at a later time. This patient responded to LADD with no further difficulty. Notably, there were no intraoperative or postoperative complications charted for the first 100 patients. Data available at 2-year follow-up yielded a surgical success rate of 86%, which was a slight improvement from the 84% surgical success rating attained at 1-year follow-up. The surgical success rate are comparable, or better than previously reported success rates, which have ranged from 55% to 85% [1,6,16–19].

Previous research examining the efficacy of LADD has yielded inconsistent findings with "at risk" groups of patients (e.g., individuals with multilevel herniations or previous surgical intervention) [15–17]. Due to the difficulty in controlling for the influence of these factors on surgical outcome, researchers have typically excluded "at risk" groups from clinical trials [15,16]. In contrast, findings from the current study revealed no differences in surgical outcome for individuals who underwent LADD for multilevel herniations. In addition, 88% of the patients who had under-

gone previous surgical intervention (i.e., open laminectomy, posterolateral fusion, chemonucleolysis) responded with Macnab ratings of "excellent" or "good." Most notably, 19 of the patients in our sample had open laminectomy suggested by either an orthopaedic surgeon or neurosurgeon and subsequently elected to undergo LADD. These patients responded to LADD with an 84% surgical success rate. The 80% success rate for individuals who required a second LADD indicates that patients may undergo a second procedure at an additional or index level and respond with "excellent" or "good" Macnab ratings without additional procedural complications.

The surgical success rates of LADD suggest that the Holmium: YAG laser with a side-firing fiber offers a relatively noninvasive surgical alternative in the treatment of select symptomatic lumbar disc disorders. Although the lack of a matched control group in this study precludes empirical comparison of LADD and traditional surgical procedures, patient ratings at follow-up and return-to-work data are suggestive that LADD should be further evaluated in a controlled fashion as an alternative treatment procedure. The current results stand in contrast to the results of other researchers, who have achieved less positive results and higher complication rates [7,15–17]. It is hypothesized that stringent patient selection and use of the Holmium:YAG laser with a side-firing fiber may have enhanced the efficacy of LADD procedures and decreased the complications noted by other researchers. Future clinical trials should incorporate standardized protocols to allow patient and procedural comparisons between researchers and laser systems. Regarding the cost effectiveness of LADD, for the current study, the cost of surgical care for a single level LADD procedure is estimated at one-third the cost of a single level lumbar disc excision [20,21]. Of great importance is the clinical nature of LADD, its lack of invasiveness, low risk of mortality and morbidity, and reduced hospital stay, which potentially translate into a cost-effective and safe alternative to traditional treatment procedures for some patients.

The seven patients deemed failures due to ratings of fair or poor included five patients who received one LADD and two patients who required an additional LADD. Notably, although these patients have not reported significant improvement in symptomatology, all have refused additional treatment and have returned to previous employment. The patients who required open laminectomy due to undetected sequestered nucleus pulposus (SNP) were also deemed failures. Although type of imaging technique (i.e., MRI, CT) varied among those patients with undetected SNP, utilization of one imaging technique across all patients would further standardize the clinical protocol. In addition, the present study utilized multiple imaging centers as a convenience to the patients. The imaging center used by each patient was not recorded; thus we are unable to specify if all patients with undetected SNP utilized the same center. Future clinical trials would do well to employ one central imaging center to control for differing procedural guidelines within each center. Also, radiographic imaging techniques are subject to error, and occasionally sequestered fragments can be obscured. For patients with questionable radiographic findings, it may be necessary to perform discography with or without CT to confirm contained disc herniation. Previous researchers have reported higher success rates for patients who underwent discography than patients who did not prior to LADD [18].

Certainly, the current study is limited by the lack of a matched control group and relatively limited follow-up period. We are currently collecting 3-year follow-up data on both the current patients as well as a new sample of patients to further assess the efficacy and safety of LADD using the Holmium: YAG laser with a side-firing fiber. In particular, it will be crucial to examine data for the subgroup of patients whose Macnab ratings declined at 2-year follow-up. As with any surgical procedure, experience can influence a surgeon's ability. The accuracy of placement of the introducer cannula, as well as the aiming and firing of the laser, are of critical importance for the safety and efficacy of LADD. We strongly advocate surgeons obtaining proctorship prior to accreditation to perform the LADD procedure.

## ACKNOWLEDGMENTS

The authors thank Jennie McCartney for invaluable support in the preparation of this manuscript.

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